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| <b>LIST OF REFERENCES CITED BY APPLICANT</b><br>(Use several sheets if necessary) | ATTY DOCKET NO.            | APPLICATION NO          |
|   | 9516-084-999               | 10/748,085              |
|   | APPLICANT<br>Muller et al. |                         |
|   | FILING DATE                | GROUP                   |
|   | 12/29/03                   | 1626<br><del>1614</del> |



## U.S. PATENT DOCUMENTS

| *EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|-----------------|------|------|-------|----------|-------------------------------|
|                      |                 |      |      |       |          |                               |
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## FOREIGN PATENT DOCUMENTS

|    |     | DOCUMENT NUMBER | DATE     | COUNTRY      | CLASS | SUBCLASS | TRANSLATION |    |
|----|-----|-----------------|----------|--------------|-------|----------|-------------|----|
|    |     |                 |          |              |       |          | YES         | NO |
| GS | B01 | WO 02/16305     | 2/28/02  | PCT          |       |          |             |    |
|    | B02 | WO 01/90076     | 11/29/01 | PCT          |       |          |             |    |
|    | B03 | WO 01/34606     | 5/17/01  | PCT          |       |          |             |    |
|    | B04 | WO 01/34603     | 5/17/01  | PCT          |       |          |             |    |
|    | B05 | WO 97/23457     | 7/3/97   | PCT          |       |          |             |    |
|    | B06 | DD 298 389      | 10/27/83 | East Germany |       |          |             |    |

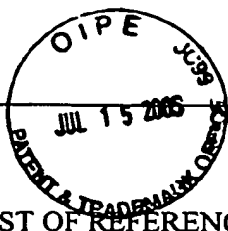
## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

|    |     |   |
|----|-----|---|
| GS | C01 | Baughman et al., 1990, "Release of tumor necrosis factor by alveolar macrophages of patients with sarcoidosis," J. Lab. Clin. Med. 115(1): 36-42  |
|    | C02 | Beavo et al., 1990, "Primary sequence of cyclic nucleotide phosphodiesterase isozymes and the design of selective inhibitors," Trends Pharmacol. Sci. 11(4): 150-155  |
|    | C03 | Beckett et al., 1996, Drug Discovery Today 1:16-26  |
|    | C04 | Berge et al., 1977, "Pharmaceutical salts," J. Pharm. Sci. 66(1): 1-19  |
|    | C05 | Bertolini et al., 1986, "Stimulation of bone resorption and inhibition of bone formation in vitro by human tumour necrosis factors," Nature 319(6053): 516-518  |
|    | C06 | Bissonnette et al., 1989, "Pulmonary inflammation and fibrosis in a murine model of asbestosis and silicosis. Possible role of tumor necrosis factor," Inflammation 13(3): 329-339  |
|    | C07 | Clouse et al., 1989, "Monokine regulation of human immunodeficiency virus-1 expression in a chronically infected human T cell clone," J. Immunol. 142(2): 431-438   |
|    | C08 | Dezube et al., 1990, "Pentoxifylline and wellbeing in patients with cancer," Lancet 335(8690):662   |
|    | C09 | Duh et al., 1989, "Tumor necrosis factor alpha activates human immunodeficiency virus type 1 through induction of nuclear factor binding to the NF-kappa B sites in the long terminal repeat," Proc. Natl. Acad. Sci. USA 86(15): 5974-5978 |
|    | C10 | Elliott et al., 1995, "TNF alpha blockade in rheumatoid arthritis: rationale, clinical outcomes and mechanisms of action," Int. J. Immunopharmacol. 17(2): 141-145  |
|    | C11 | Ferrai-Baliviera et al., 1989, "Tumor necrosis factor induces adult respiratory distress syndrome in rats," Arch. Surg. 124(12): 1400-1405  |
|    | C12 | Folks et al., 1989, "Tumor necrosis factor alpha induces expression of human immunodeficiency virus in a chronically infected T-cell clone," Proc. Natl. Acad. Sci. USA 86(7): 2365-2368  |
|    | C13 | Grau et al., 1989, "Tumor necrosis factor and disease severity in children with falciparum malaria," N. Engl. J. Med. 320(24):1586-91   |
|    | C14 | Grewe et al., 1982, "Elevated leukocyte cyclic AMP-phosphodiesterase in atopic disease: a possible mechanism for cyclic AMP-agonist hyporesponsiveness," J. Allergy Clin. Immunol. 70(6): 452-457   |

|    |     |   |
|----|-----|---|
| GS | C15 | Guay et al., 2002, "Discovery of L-791,943: a potent, selective, non emetic and orally active phosphodiesterase-4 inhibitor," Bioorg. Med. Chem. Lett. 12(11): 1457-1461  |
|    | C16 | Hanifin et al., 1996, "Type 4 Phosphodiesterase Inhibitors Have Clinical and in vitro Anti-inflammatory Effects in Atopic Dermatitis," J. of Investigative Dermatology 107(1):51-56   |
|    | C17 | Hatzelmann et al., 2001, "Anti-inflammatory and immunomodulatory potential of the novel PDE4 inhibitor roflumilast in vitro," J. Pharmacol. Exp. Ther. 297(1):267-279   |
|    | C18 | Hinshaw et al., 1990, "Survival of primates in LD100 septic shock following therapy with antibody to tumor necrosis factor (TNF alpha)," Circ. Shock 30(3):279-292  |
|    | C19 | Holler et al., 1990, "Increased serum levels of tumor necrosis factor alpha precede major complications of bone marrow transplantation," Blood 75(4): 1011-1016   |
|    | C20 | Houslay et al., 1998, "The multienzyme PDE4 cyclic adenosine monophosphate-specific phosphodiesterase family: intracellular targeting, regulation, and selective inhibition by compounds exerting anti-inflammatory and antidepressant actions," Adv. Pharmacol. 44:225-342 |
|    | C21 | Huang et al., 2001, "The Next Generation of PDE4 inhibitors," Curr. Opin. Chem. Biol. 5:432-438   |
|    | C22 | Johnson et al., 1989, "Tumors producing human tumor necrosis factor induced hypercalcemia and osteoclastic bone resorption in nude mice," Endocrinology 124(3):1424-1427  |
|    | C23 | List et al., 1990, "The myelodysplastic syndromes: biology and implications for management," J. Clin. Oncol. 8(8):1424-1441   |
|    | C24 | Lowe et al., 1992, Drugs of the Future 17(9):799-807  |
|    | C25 | Millar et al., 1989, "Tumour necrosis factor in bronchopulmonary secretions of patients with adult respiratory distress syndrome," Lancet 2(8665):712-714   |
|    | C26 | Monte et al., 1990, "Productive human immunodeficiency virus-1 infection of megakaryocytic cells is enhanced by tumor necrosis factor-alpha," Blood 79(10): 2670-2679   |
|    | C27 | Piguet et al., 1990, "Requirement of tumour necrosis factor for development of silica-induced pulmonary fibrosis," Nature 344(6263):245-247   |
|    | C28 | Poli et al., 1990, "Tumor necrosis factor alpha functions in an autocrine manner in the induction of human immunodeficiency virus expression," Proc. Natl. Acad. Sci. USA 87(2): 782-785  |
|    | C29 | Poli et al., 1992, "The effect of cytokines and pharmacologic agents on chronic HIV infection," AIDS Res. Hum. Retroviruses 8(2):191-197  |
|    | C30 | Rice et al., 1989, "An inducible endothelial cell surface glycoprotein mediates melanoma adhesion," Science 246(4935):1303-1306   |
|    | C31 | Shealy et al., 1968, "Synthesis of D- and L-thalidomide and related studies," J. Pharm. Sci. 57(5):757-764  |
|    | C32 | Shealy et al., 1965, "D- and L-thalidomide," Chem. Ind. 24:1030-1031  |
|    | C33 | Tiemey et al., ed., 1998, Curr. Med. Diag. Treat. 37th ed., 499   |
|    | C34 | Tracey et al., 1987, "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," Nature 330(6149):662-664  |
|    | C35 | Verghese et al., 1995, "Differential regulation of human monocyte-derived TNF alpha and IL-1 beta by type IV cAMP-phosphodiesterase (cAMP-PDE) inhibitors," J. Pharmacol. Exp. Ther. 272(3): 1313-1320  |
| ✓  | C36 | Van Dullemen et al., 1995, "Treatment of Crohn's disease with anti-tumor necrosis factor chimeric monoclonal antibody (cA2)," Gastroenterology 109(1):129-135   |

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|----------|------------------------------|-----------------|------------|
| EXAMINER | /Golam Shameem/ (07/18/2006) | DATE CONSIDERED | 07/18/2006 |
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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Sheet 1 of 1

**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

ATTY DOCKET NO.  
9516-084-999  
(501872-999083)

APPLICATION NO.  
10/748,085

APPLICANT  
Muller *et al.*

CONFIRMATION NO.:  
6852

FILING DATE  
December 29, 2003

GROUP 1626  
~~1614~~

**U.S. PATENT DOCUMENTS**

| *EXAMINER<br>INITIAL |     | DOCUMENT NUMBER | DATE     | NAME                 | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|-----|-----------------|----------|----------------------|-------|----------|-------------------------------|
| GS                   | A01 | 6,214,857       | 04/10/01 | Muller <i>et al.</i> |       |          |                               |
| GS                   | A02 | 6,326,388       | 12/04/01 | Man <i>et al.</i>    |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

|  |  | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION      |
|--|--|-----------------|------|---------|-------|----------|------------------|
|  |  |                 |      |         |       |          | YES NO           |
|  |  |                 |      |         |       |          | Abstract<br>only |

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

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